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July 23, 1998

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket No. 98N-0222
Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices
63 Fed. Reg. 31143 (June 8, 1998)

The American Association of Retired Persons (AARP) submits the following comments on the FDA's proposed rule regarding the dissemination of information on unapproved uses for drugs, biologics and devices. FDA's disposition of this issue will have a significant impact on AARP's membership, which constitutes a substantial portion of the consumers who use FDA-regulated products.

Distribution by drug manufacturers of information about unapproved ("off-label") uses has been a controversial issue for years. AARP has consistently expressed concern about promotion of off-label uses by manufacturers because we believe that it could seriously undermine the approval process and FDA's important role in ensuring the safety and efficacy of drugs and other products. Congress, however, has spoken on the issue and, in the Food and Drug Administration Modernization Act of 1997 (FDAMA), directs FDA to establish a process by which information about off-label uses can be disseminated. Section 401 of FDAMA provides significant detail about how the information dissemination process should operate; this level of detail is intended to ensure that dissemination of off-label use information is carefully controlled.

In general, AARP supports FDA's proposed rule implementing section401, because we believe that it contains steps that appropriately limit any opportunities to abuse the dissemination process. We do, however, have two general concerns that we want to emphasize:

- **Adequate Enforcement -** The key to the effectiveness of the off-label use "proapproval" process established in the proposed rule is adequate oversight and enforcement by FDA. Of particular concern is the provision in the proposed rule that exempts manufacturers from submitting a supplemental use application when to conduct the necessary studies would be unethical or economically unfeasible. We believe that FDA's proposed approach in defining "economically unfeasible" is reasonable and consistent with Congress's intent to make the

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98N-0222 C34

"economically unfeasible" is reasonable and consistent with Congress's intent to make the granting of this exemption rare. We urge the agency to resist any pressure from manufacturers to lessen their burden of proof for establishing the economically based exemption. In addition, adequate resources to oversee this effort will be critical to the successful implementation of this rule. It will be essential for FDA to direct resources to this effort and for the Congress to make adequate resources available.

- **Public Access to Information -** FDA's proposed rule requires manufacturers to submit detailed information in support of an unapproved use. Given the fact that these submissions will be supporting a use that has yet to be declared safe and effective by the FDA, it is incumbent upon the agency to grant the public access to manufacturers' submissions. Public access to these materials provides an added layer of protection against the dissemination of information about an inadequate y substantiated, unapproved use.

We appreciate this opportunity to comment on the proposed rule. If you have any questions, please contact Mila Becker at (202) 434-3772 in our Federal Affairs staff.

Sincerely,

Martin Corry
Director, Federal Affairs